

R E M A R K S

Claims 55-73 are currently pending in the present application. In the instant Office Action, the Examiner raised a single issue regarding the patentability of the pending claims:

- 1) Claims 67-73 stand rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Peterson *et al.* (U.S. Patent No. 5,730,777) in view of Csete *et al.* (U.S. Patent No. 6,184,035) and Trexler (U.S. Patent No. 4,026,286).

Applicants thank the Examiner for indicating that Claims 57-66 are allowable. In addition, Applicants hereby amend Claim 67, in order to further the prosecution of the present application and Applicants' business interests, yet without acquiescing to the Examiner's arguments. Applicants reserve the right to prosecute the original, similar, or broader claims in one or more future application(s). These amendments do not introduce new matter and do not narrow the scope of any of the claims within the meaning of *Festo*.¹

1) The Claims Are Nonobvious

The Examiner has rejected Claims 67-73 under 35 U.S.C. § 103(a) as allegedly unpatentable over Peterson *et al.* (U.S. Patent No. 5,730,777) in view of Csete *et al.* (U.S. Patent No. 6,184,035) and Trexler (U.S. Patent No. 4,026,286). The Examiner states:

Peterson et al and Csete et al. disclose the claim[ed] method except for the step of transporting the transplant material in said device. Trexler teaches the use of isolated environments and shows a device (Figure 1) in which the device and all equipment needed for its operation are on a structure that is on wheels. This would inherently allow for the device to be movable to any desired location and not be restricted to only one area. Therefore[,] a modification of Peterson et al such that the structure be provided with wheels, as taught by Trexler, would have been obvious since this would allow the device to be movable to move the device to any desired location and/or transport whatever is in the isolated environment to any location needed without affecting the isolated environment or the material inside the environment (Office Action, page 2).

Applicants must respectfully disagree that the claimed invention is obvious. Nonetheless, Applicants have amended Claim 67, in order to further the prosecution of the present application

¹ *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 122 S.Ct. 1831, 1838, 62 USPQ2d 1705, 1710 (2002).

and Applicants' business interests, yet without acquiescing to the Examiner's arguments, and while reserving the right to prosecute the original, similar, or broader claims in one or more future application(s). Specifically, Applicants have amended Claim 67 to recite that said device comprises "an airlock for attaching said device to a controlled surgery environment." Support for this amendment is found in the application as filed, which teaches that the controlled transport environment or "CTE is docked via the airlock to the [controlled surgery environment] CSE in which the donor organs/tissues are removed" (Specification, at page 16, lines 1 and 2).

The Examiner is reminded that a *prima facie* case of obviousness requires: (a) some suggestion or motivation to combine the reference teachings, (b) a reasonable expectation of success, and (c) a teaching or suggestion of all claim limitations. Moreover, the teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure (MPEP, 2143). Applicants respectfully submit that the Examiner has failed to establish one or more elements of a *prima facie* case of obviousness.

No Suggestion or Motivation to Combine the References

The mere fact that the references can be combined does not render the resultant modification obvious, unless the prior art also suggests the desirability of the modification.² In the first place, Peterson (of U.S. **class 95/12**) is directed methods for manipulating biological material in a cell culture hood, while Csete (of U.S. **class 435/377**) is directed to methods for culturing stem cells in an incubator. In contrast, Trexler (of U.S. **class 128/04**) is directed to methods for transferring objects through medical isolators having a transfer port comprising a sleeve and an air permeable membrane (Trexler, abstract). Applicants assert that since Peterson and Csete are directed to different types of methods (e.g., cell culture) than Trexler (e.g., surgical), and hence are directed to solving distinct problems, the requisite motivation to combine the references is lacking.

Importantly, the teachings of the references are not sufficient to render the claims obvious when the proposed modification or combination of the prior art changes the principle of

² See, *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990).

operation of the prior art invention.³ Applicants contend that the Examiner's modification of Peterson such that the structure be provided with wheels, as taught by Trexler, changes the principle of operation of Peterson's device, and thus does not provide the methods of amended Claims 67-73 comprising providing a (portable) device for transporting transplant material. Peterson describes the bulky device of Figures 1-3 as a "*workbench* according to the invention wherein a housing comprising inner first chamber walls 1 encloses a first chamber 2 containing a gaseous atmosphere" (Peterson, at column 18, lines 42-45, emphasis added). Peterson adds "[t]he housing according to the invention may be produced of any *material known from the production of incubators and working benches such as stainless steel* (Peterson, at column 14, lines 46-48, emphasis added). Moreover, the workbench of Peterson shown in Figure 1 is connected to two gas supplies (7 and 18), a filter (38), a compressor (34) and a central control unit (10), which is in communication with a computer (51). Placing wheels on Peterson's workbench to use it as a portable device for transporting transplant material changes the principle of operation of this device such that it no longer functions as a component of a system having multiple external, and central components.

No Teaching or Suggestion of All Claim Limitations

Additionally, the combination of Peterson, Csete and Trexler does not teach or suggest all of the limitations of amended Claims 67-73. In particular, neither Peterson, Csete nor Trexler provide devices comprising **an air lock for attaching the device to a controlled surgery environment**.

As a *prima facie* case of obviousness has not been established, Applicants respectfully request that this rejection be withdrawn.

CONCLUSION

Applicants believe the arguments set forth above traverse the Examiner's rejections and, therefore request that a timely Notice of Allowance be issued in this case. However, should the

³ See, *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959).

Examiner believe that a telephone interview would aid in the prosecution of this application,
Applicants encourage the Examiner to call the undersigned collect.

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